

In the Claims

Please replace all prior versions, and listings, of claims in the application with the following list of claims:

1. (Currently amended) A method for producing a therapeutic effect, comprising: administering to a pulmonary tissue of a subject an unformulated dry polysaccharide particle in an effective amount for producing a therapeutic effect, wherein the unformulated dry polysaccharide particle has a mean geometric diameter of 1-500 microns, and wherein the unformulated dry polysaccharide is a therapeutic polysaccharide.
2. (Original) The method of claim 1, wherein the polysaccharide is a glycosaminoglycan.
3. (Original) The method of claim 2, wherein the glycosaminoglycan is a heparin.
4. (Original) The method of claim 2, wherein the glycosaminoglycan is a heparin sulfate.
5. (Original) The method of claim 2, wherein the glycosaminoglycan is a low molecular weight heparin.
6. (Original) The method of claim 3, wherein the heparin is a biotechnology derived heparin.
7. (Original) The method of claim 3, wherein the heparin is a chemically modified heparin.
8. (Original) The method of claim 2, wherein the glycosaminoglycan is a heparin analogue.
9. (Previously presented) The method of claim 8, wherein the heparin analogue is selected from the group consisting of an AT-III binding oligosaccharide and an AT-III binding pentasaccharide.
10. (Original) The method of claim 2, wherein the glycosaminoglycan is an unfractionated heparin preparation.

11. (Original) The method of claim 1, wherein the unformulated dry polysaccharide particle has a mean geometric diameter of 1-200 microns.

12. (Original) The method of claim 1, wherein the unformulated dry polysaccharide particle has a mean geometric diameter of 1-53 microns.

13. (Original) The method of claim 1, wherein the unformulated dry polysaccharide particle has a mean geometric diameter of 53-106 microns.

14. (Original) The method of claim 1, wherein the unformulated dry polysaccharide particle has a mean geometric diameter of 1-5 microns.

15. (Original) The method of claim 1, wherein the unformulated dry polysaccharide particle has a mean aerodynamic diameter of 1-5 microns.

16. (Original) The method of claim 1, wherein the unformulated dry polysaccharide particle has a mean aerodynamic diameter selected from the group consisting of 5-35 and 35-75 microns.

17. (Currently amended) The method of claim 2, wherein the subject has or is at risk of a coagulation disorder and the therapeutic effect of the glycosaminoglycan is anti-coagulation or antithrombosis.

18. (Original) The method of claim 17, wherein the coagulation disorder is selected from the group consisting of thrombosis associated with cardiovascular disease and vascular conditions.

19. (Original) The method of claim 18, wherein the cardiovascular disease is selected from the group consisting of acute myocardial infarction, unstable angina, and atrial fibrillation.

20. (Original) The method of claim 18, wherein the vascular condition is selected from the group consisting of deep venous thrombosis, stroke, and pulmonary embolism.

21. (Original) The method of claim 17, wherein the glycosaminoglycan is administered in an amount effective to produce a minimum therapeutic level of approximately 0.2 IU/ml anti-factor Xa activity.

22. (Original) The method of claim 2, wherein the subject is preparing to undergo, is undergoing or is recovering from a surgical procedure.

23. (Original) The method of claim 22, wherein the surgical procedure is selected from the group consisting of cardiac-pulmonary by-pass surgery, coronary revascularization surgery, orthopedic surgery, and prosthesis replacement surgery.

24. (Currently amended) The method of claim 2, wherein the subject has ~~or is at risk of~~ atherosclerosis.

25. (Currently amended) The method of claim 2, wherein the subject has ~~or is at risk of~~ a respiratory disorder.

26. (Original) The method of claim 25, wherein the respiratory disorder is selected from the group consisting of asthma, emphysema, adult respiratory distress syndrome (ARDS), and lung reperfusion injury.

27. (Currently amended) The method of claim 2, wherein the subject has ~~or is at risk of~~ developing a cancer or metastasis.

28. (Currently amended) The method of claim 2, wherein the subject has ~~or is at risk of~~ developing an inflammatory disorder.

29. (Currently amended) The method of claim 2, wherein the subject has ~~or is at risk of~~ developing an allergy.

30. (Currently amended) The method of claim 2, wherein the subject has ~~or is at risk of~~ developing an angiogenic disorder and the glycosaminoglycan is administered in an effective amount for preventing angiogenesis.

31. (Currently amended) The method of claim [[2]]30, wherein the angiogenic disorder is selected from the group consisting of neovascular disorders of the eye, osteoporosis, psoriasis, and arthritis.

32. (Original) The method of claim 1, wherein the polysaccharide is selected from the group consisting of chondroitin sulfate, dermatan sulfate, hyaluronic acid, Pectin, pectin derivatives, oligosaccharides and pentasaccharides that bind to AT-III.

33. (Original) The method of claim 1, wherein the unformulated dry polysaccharide is self administered by the subject.

34. (Original) The method of claim 1, wherein the unformulated dry polysaccharide is administered through a tracheal tube.

35. (Original) The method of claim 2, wherein the subject is undergoing a tissue or organ transplant.

36. (Original) The method of claim 1, wherein the unformulated dry polysaccharide has a tap density of 0.01 - 0.4 g/cm³.

37. (Original) The method of claim 1, wherein the unformulated dry polysaccharide has a tap density of greater than 0.4 g/cm³.

38. (Currently amended) A method for delivering at least 5% of a therapeutic polysaccharide to lower respiratory tract, comprising:

administering to a pulmonary tissue of a subject an unformulated dry polysaccharide particle, wherein the unformulated dry polysaccharide particle has a mean geometric diameter of 1-500 microns, and wherein at least 5% of the polysaccharide administered is delivered to the lower respiratory tract, and wherein the polysaccharide is a therapeutic polysaccharide.

39-41. (Canceled)

42. (Currently amended) A method for systemically delivering a therapeutic polysaccharide to a subject, comprising:

administering to a pulmonary tissue of the subject an unformulated dry polysaccharide particle, wherein the unformulated dry polysaccharide particle has a mean geometric diameter of 1-500 microns, and wherein the unformulated dry polysaccharide particle is delivered systemically, and wherein the unformulated dry polysaccharide is a therapeutic polysaccharide.

43. (Currently amended) An unformulated dry heparin-like glycosaminoglycan having a mean geometric diameter of 1-500 microns.

44-57. (Cancelled)

58. (Currently amended) A method for delivering a heparin-like glycosaminoglycan to a subject, comprising, administering to a pulmonary tissue of a subject the compositionheparin-like glycosaminoglycan of claim 43.

59. (Currently amended) A method of rapidly delivering a therapeutic polysaccharide to a subject comprising:

administering a dry aerosol containing a therapeutic polysaccharide to a pulmonary tissue of a subject in an effective amount to produce a peak plasma concentration of therapeutic polysaccharide within two hours.

60-72. (Cancelled)

73. (Currently amended) A method of rapidly delivering a therapeutic polysaccharide to a subject comprising:

administering a dry aerosol containing a therapeutic polysaccharide to a pulmonary tissue of a subject in an effective amount to deliver at least 5% of the therapeutic polysaccharide to the blood within one hour.

74-78. (Cancelled)

79. (Currently amended) A method for producing a rapid therapeutic effect, comprising: administering a dry aerosol containing a therapeutic polysaccharide to a pulmonary tissue of a subject in an effective amount for producing a therapeutic effect within 1 hour of administration.

80-81. (Canceled)

82. (Original) A composition comprising a dry aerosol formulation of particles containing a heparin-like glycosaminoglycan, wherein the particles have a mean geometric diameter of greater than 30 microns.

83-88. (Canceled)

89. (Original) A composition comprising a dry aerosol formulation of particles containing a heparin-like glycosaminoglycan, wherein the particles have a mean aerodynamic diameter of greater than 5 microns.

90. (Original) A composition comprising a dry aerosol formulation of particles containing a heparin-like glycosaminoglycan, wherein the particles have a tap density of greater than 0.4 g/cm³.

91. (Currently amended) A kit for administering a dry aerosol containing a polysaccharide to the respiratory tract of a subject comprising:

an inhalation apparatus,
polysaccharide dry aerosol particle formulation, wherein the polysaccharide dry aerosol particle is formulated to release at least 5% of the polysaccharide within 2 hours and
a detection system to determine the level of the polysaccharide administered.

92-98. (Canceled)

99. (Original) A method for delivering a polysaccharide to a subject, comprising: administering to a pulmonary tissue of the subject a dry aerosol formulation comprising an unformulated dry glycosaminoglycan preparation and a formulated dry glycosaminoglycan preparation to deliver the polysaccharide to the subject.

100-112. (Canceled)

113. (Currently amended) The method of claim 38, wherein at least 10% of the therapeutic polysaccharide administered is delivered to the lower respiratory tract.

114. (Currently amended) The method of claim 38, wherein at least 30% of the therapeutic polysaccharide administered is delivered to the lower respiratory tract.

115. (Currently amended) The method of claim 38, wherein at least 50% of the therapeutic polysaccharide administered is delivered to the lower respiratory tract.

116. (Currently amended) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 1-200 microns.

117. (Currently amended) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 1-53 microns.

118. (Currently amended) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 1-5 microns.

119. (Currently amended) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 5-53 microns.

120. (Currently amended) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the unformulated dry heparin-like glycosaminoglycan has a mean geometric diameter of 53-106 microns.

121. (Currently amended) The unformulated dry heparin-like glycosaminoglycan of claim 43, wherein the heparin-like glycosaminoglycan is selected from the group consisting of a heparin, a heparin

sulfate, a low molecular weight heparin, a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.

122. (Currently amended) A composition, comprising:

the unformulated dry heparin-like glycosaminoglycan of claim 43 and a formulated dry glycosaminoglycan preparation.

123. (Previously Presented) The composition of claim 122, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is selected from the group consisting of a heparin, a heparin sulfate, a low molecular weight heparin, a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.

124. (Currently amended) The composition of claim 122, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is the same as the glycosaminoglycan of the unformulated dry heparin-like glycosaminoglycan preparation.

125. (Currently amended) The composition of claim 122, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is different than the glycosaminoglycan of the unformulated dry heparin-like glycosaminoglycan preparation.

126. (Previously Presented) The composition of claim 122, wherein the formulated dry glycosaminoglycan preparation includes a polymer to effect slow release of the glycosaminoglycan.

127. (Previously Presented) The composition of claim 126, wherein the polymer is selected from the group consisting of PLA, PGA, and PLGA.

128. (Previously Presented) The composition of claim 122, wherein the formulated dry glycosaminoglycan preparation includes a surfactant.

129. (Previously Presented) The composition of claim 128, wherein the surfactant is DPPC.

130. (Currently amended) A method of claim 73, wherein at least 10% of the therapeutic polysaccharide is delivered to the blood within one hour.

131. (Currently amended) The method of claim 73, wherein at least 20% of the therapeutic polysaccharide is delivered to the blood within one hour.

132. (Currently amended) The method of claim 73, wherein at least 40% of the therapeutic polysaccharide is delivered to the blood within one hour.

133. (Currently amended) The method of claim 73, wherein at least 50% of the therapeutic polysaccharide is delivered to the blood within one hour.

134. (Currently amended) A method of claim 73, wherein at least 10% of the therapeutic polysaccharide is detectable in the blood within one hour.

135. (Previously Presented) The composition of claim 82, wherein the particles are spherical.

136. (Previously Presented) The composition of claim 82, wherein the particles are non-spherical.

137. (Previously Presented) The composition of claim 82, wherein the particles are porous.

138. (Previously Presented) The composition of claim 82, wherein the particles are non-porous.

139. (Previously Presented) The composition of claim 82, further comprising a surfactant.

140. (Previously Presented) The composition of claim 82, further comprising a polymer to effect slow release of the heparin-like glycosaminoglycan.

141-157. (Canceled)

158. (Currently amended) The method of claim 59, wherein dry aerosol containing a therapeutic polysaccharide is administered in an effective amount to produce the peak concentration or activity of therapeutic polysaccharide within one and one half hours.

159. (Currently amended) The method of claim 59, wherein dry aerosol containing a therapeutic polysaccharide is administered in an effective amount to produce the peak concentration or activity of therapeutic polysaccharide within one hour.

160. (Currently amended) The method of claim 59, wherein dry aerosol containing a therapeutic polysaccharide is administered in an effective amount to produce the peak concentration or activity of therapeutic polysaccharide within one half hour.

161. (Currently amended) The method of claim 59, wherein the therapeutic polysaccharide is a glycosaminoglycan.

162. (Previously presented) The method of claim 161, wherein the glycosaminoglycan is selected from the group consisting of a low-molecular-weight heparin, heparin, heparin sulfate, biotechnology derived heparin, chemically modified heparin, heparin analogue, and unfractionated heparin preparation.

163. (Previously presented) The method of claim 59, wherein the dry aerosol contains an unformulated dry polysaccharide.

164. (Previously presented) The method of claim 59, wherein the dry aerosol contains a dry polysaccharide formulated in a surfactant.

165. (Previously presented) The method of claim 164, wherein the surfactant is DPPC.

166. (Previously presented) The method of claim 164, wherein the surfactant is coated on the particle surface.

167. (Previously presented) The method of claim 164, wherein the surfactant is incorporated into the formulation.

168. (Previously presented) The method of claim 59 further comprising administering an additional therapeutic agent.

169. (Previously presented) The method of claim 168, wherein the additional therapeutic agent is selected from the group consisting of proteins, peptides, nucleic acids, and small organic molecules.

170. (Previously presented) The method of claim 59, wherein the dry aerosol containing a polysaccharide includes both a formulated and an unformulated dry polysaccharide.

171-175. (Canceled)

176. (Previously presented) The method of 79, wherein the dry aerosol is administered in an effective amount for producing a therapeutic effect within 15 minutes of administration.

177. (Previously presented) The method of 79, wherein the dry aerosol is administered in an effective amount for producing a therapeutic effect within 10 minutes of administration.

178-183. (Canceled)

184. (Previously presented) The kit of claim 91, wherein the polysaccharide is a glycosaminoglycan.

185. (Previously presented) The kit of claim 184, wherein the glycosaminoglycan is selected from the group consisting of a low-molecular-weight heparin, heparin, heparin sulfate, biotechnology derived heparin, chemically modified heparin, heparin analogue and unfractionated heparin preparation.

186. (Previously presented) The kit of claim 91, wherein the mean geometric diameter of the particles is between 1 and 500 μm .

187. (Previously presented) The kit of claim 91, wherein the mean geometric diameter of the particles is between 1 and 106 μm .

188. (Previously presented) The kit of claim 91, wherein the mean geometric diameter of the particles is between 5 and 53 μm .

189. (Previously presented) The kit of claim 91, wherein the aerodynamic diameter of the particles is between 1 and 5 μm .

190. (Previously presented) The kit of claim 91, wherein the aerodynamic diameter of the particles is selected from the group consisting of 5-35 and 35-75 microns..

191. (Previously presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 90:10.

192. (Previously presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 70:30.

193. (Previously presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 50:50.

194. (Previously presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 30:70.

195. (Previously presented) The method of claim 99, wherein the ratio of unformulated preparation to formulated preparation is 10:90.

196. (Currently amended) The method of claim 99, wherein the polysaccharide is a glycosaminoglycan ~~and the glycosaminoglycan~~ is selected from the group consisting of a heparin, a heparin sulfate, a low molecular weight heparin, a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.

197. (Previously presented) The method of claim 196, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is the same as the glycosaminoglycan of the unformulated dry glycosaminoglycan preparation.

198. (Previously presented) The method of claim 196, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is different than the glycosaminoglycan of the unformulated dry glycosaminoglycan preparation.

199. (Previously presented) The method of claim 99, wherein the formulated dry glycosaminoglycan preparation includes a polymer to effect slow release of the glycosaminoglycan.

200. (Previously presented) The method of claim 199, wherein the polymer is selected from the group consisting of PLA, PGA, and PLGA.

201. (Previously presented) The method of claim 99, wherein the formulated dry glycosaminoglycan preparation includes a surfactant.

202. (Previously presented) The method of claim 201, wherein the surfactant is DPPC.

203. (Previously presented) The method of claim 99, wherein the relative ratio of formulated to unformulated preparation is selected from the group consisting of 10:90, 20:80, 30:70, 40:60, 50:50, 60:40, 70:30, 80:20, and 90:10.

204. (New) An unformulated dry glycosaminoglycan having a mean geometric diameter of 10-500 microns.

205. (New) A method for delivering a glycosaminoglycan to a subject, comprising, administering to a pulmonary tissue of a subject the glycosaminoglycan of claim 204.

206. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 10-250 microns.

207. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 10-100 microns.

208. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 100-200 microns.

209. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 100-150 microns.

210. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 53-106 microns.

211. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 20-53 microns.

212. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 53-75 microns.

213. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the unformulated dry glycosaminoglycan has a mean geometric diameter of 75-106 microns.

214. (New) The unformulated dry glycosaminoglycan of claim 204, wherein the glycosaminoglycan is selected from the group consisting of a heparin, a heparin sulfate, a low molecular weight heparin, a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.

215. (New) A composition, comprising:
the unformulated dry glycosaminoglycan of claim 204 and a formulated dry glycosaminoglycan preparation.

216. (New) The composition of claim 215, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is selected from the group consisting of a heparin, a heparin sulfate, a low molecular weight heparin, a biotechnology derived heparin, a chemically modified heparin, a heparin analogue, and an unfractionated heparin preparation.

217. (New) The composition of claim 215, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is the same as the glycosaminoglycan of the unformulated dry glycosaminoglycan preparation.

218. (New) The composition of claim 215, wherein the glycosaminoglycan of the formulated dry glycosaminoglycan preparation is different than the glycosaminoglycan of the unformulated dry glycosaminoglycan preparation.

219. (New) The composition of claim 215, wherein the formulated dry glycosaminoglycan preparation includes a polymer to effect slow release of the glycosaminoglycan.

220. (New) The composition of claim 219, wherein the polymer is selected from the group consisting of PLA, PGA, and PLGA.

221. (New) The composition of claim 215, wherein the formulated dry glycosaminoglycan preparation includes a surfactant.

222. (New) The composition of claim 221, wherein the surfactant is DPPC.